

**38 CFR Part 17****RIN 2900-AQ97****Informed Consent and Advance Directives****AGENCY:** Department of Veterans Affairs.**ACTION:** Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, without changes, an interim final rule, as amended by a second interim final rule, that amended VA's regulation regarding informed consent and advance directives. VA amended the regulation by reorganizing it and amending language where necessary to enhance clarity; and made changes to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witness requirements for a VA Advance Directive. VA has also clarified the roles and responsibilities of the practitioner and other members of the health care team pertaining to the informed consent process.

DATES: This rule is effective August 2, 2022.

FOR FURTHER INFORMATION CONTACT: Lucinda Potter, MSW, LSW, Director of Ethics Policy, National Center for Ethics in Health Care (10ETH), Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; 484-678-5150. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Interim Final Rule Published at 85 Federal Register (FR) 31690 (May 20, 2020)

In a document published in the FR on May 27, 2020, 85 FR 31690, VA amended its regulation (§ 17.32 of title 38, Code of Federal Regulations (CFR)) concerning informed consent and advance directives by reorganizing § 17.32 and revising language where necessary to enhance clarity; and making changes to facilitate the informed

consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witness requirements for a VA Advance Directive. VA provided a 60-day comment period, which ended on July 27, 2020. One comment was received; however, it did not raise any issues within the scope of the rulemaking. We make no changes based on that comment.

We note that as part of that rule, we invited public comment on whether VA should consider inclusion of emancipated minors among those listed as next-of-kin or with respect to any situations that might arise with respect to an emancipated minor (e.g., a spouse who is an emancipated minor under the age of 18). Currently, next-of-kin must be 18 years of age or older. We received no public comment on this issue and make no changes to 38 CFR 17.32 regarding emancipated minors.

Interim Final Rule Published at 87 FR 6425 (February 4, 2022)

In a document published in the FR on February 4, 2022, 87 FR 6425, VA amended § 17.32(c)(6) to clarify that the practitioner is ultimately responsible for the informed consent process but may delegate elements of the informed consent process to trained personnel. VA provided a 60-day comment period, which ended on April 5, 2022. One comment was received, which was supportive of the rule. We thank the commenter for their support. We make no changes based on that comment.

Based on the rationale set forth in both interim final rules and in this final rule, VA is adopting, as final without changes, the rule published at 85 FR 31690, as amended by 87 FR 6425.

Administrative Procedure Act

VA has considered all relevant input and information contained in the comments submitted in response to the interim final rules (85 FR 31690 and 87 FR 6425) and, for

the reasons set forth in the discussion further above, has concluded that no changes to the interim final rule at 85 FR 31690, as amended by 87 FR 6425, are warranted. Accordingly, based upon the authorities and reasons set forth in the interim final rules (85 FR 31690 and 87 FR 6425), as supplemented by the additional reasons provided in this document in response to comments received, VA is adopting the provisions of the interim final rule at 85 FR 31690, as amended by 87 FR 6425, as a final rule without changes.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612, because it affects only the informed consent process and use of advance directives within the VA health care system.

Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Except for emergency approvals under 44 U.S.C. 3507(j), VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The interim final rule (85 FR 31690) included a provision constituting revisions to an existing collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) that require approval by the Office of Management and Budget (OMB) (the provision in the interim final rule is 38 CFR 17.32). Accordingly, under 44 U.S.C. 3507(d), VA submitted a copy of the interim final rule (85 FR 31690) to OMB for review, and VA requested that OMB approve the revised collection of information on an emergency basis. VA did not receive any comments on the collection of information contained in the interim final rule (85 FR 31690). OMB approved the collections of information under control number 2900-0556.

Assistance Listing

The Assistance numbers and titles for the programs affected by this document are 64.008 – Veterans Domiciliary Care; 64.011 – Veterans Dental Care; 64.012 – Veterans Prescription Services; 64.013 – Veterans Prosthetic Appliances; 64.014 – Veterans State Domiciliary Care; 64.015 – Veterans State Nursing Home Care; 64.024 – VA Homeless Providers Grant and Per Diem Program; 64.026 – Veterans State Adult Day Health Care; 64.029 – Purchase Care Program; 64.039 – CHAMPVA; 64.040 – VHA Inpatient Medicine; 64.041 – VHA Outpatient Specialty Care; 64.042 – VHA Inpatient Surgery; 64.043 – VHA Mental Health Residential; 64.044 – VHA Home Care; 64.045 – VHA Outpatient Ancillary Services; 64.046 – VHA Inpatient Psychiatry; 64.047 – VHA Primary Care; 64.048 – VHA Mental Health clinics; 64.049 – VHA Community Living Center; 64.050 – VHA Diagnostic Care; 64.054 – Research and Development.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental

health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on July 25, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

PART 17 – MEDICAL

For the reasons set forth in the preamble, VA adopts as final the interim final rule published at 85 FR 31690 (May 27, 2020), as amended by 87 FR 6425 (February 4, 2022).

Consuela Benjamin,
Regulations Development Coordinator,
Office of Regulation Policy & Management,
Office of General Counsel,
Department of Veterans Affairs.